

REMARKS

Claims 1, 2, 4, 6 and 8-37 are pending in this application. Claims 11 to 15 and 20 are canceled herein without prejudice or disclaimer, and claims 1, 16, 17, 19, 21-23 and 37 are amended. Upon entry of this amendment, claims 1, 2, 4, 6, 8-10, 16-19 and 21-37 will be pending. Entry of this amendment and reconsideration of the rejections are respectfully requested.

No new matter has been introduced by this Amendment.

Claim 1 has been amended to require, in addition to already recited components (A) and (B), “silicone compound (C) being tris(trimethylsiloxy)silylpropyl(meth)acrylate; and an N-substituted acrylamide (D).” Support for this amendment may be found, for example, in original claims 14 and 15. Independent method claims 19 and 37 have also each been amended to require these components (C) and (D) in the mixed solution of step (a).

Claims 11-12 are objected to as being of improper dependent form for failing to further limit the subject matter of a previous claim. (Office action page 2)

The objection is moot in view of the cancellation of claims 11 and 12 without prejudice or disclaimer.

Claims 1-2, 4, 6 and 8-18 are rejected under 35 U.S.C. §103(a) as being unpatentable over Iwata et al. (US 2002/0016383) in view of Shibata et al. (US 4,547,543), when taken with Katagiri et al. (JP 06-214197) (English machine translation of Katagiri et al. (JP 06-214197) was used). (Office action page 3)

The rejection of claims 13-15 is moot in view of the cancellation of these claims without prejudice or disclaimer. Reconsideration of the rejection of the pending claims is respectfully requested in view of the amendment to claim 1. As noted above, claim 1 has been amended to require, in addition to components (A) and (B), "silicone compound (C) being tris(trimethylsiloxy)silylpropyl(meth)acrylate; and an N-substituted acrylamide (D)."

Neither Iwata et al. nor Shibata et al. teaches the combined use of components (B) and (D) according to the present invention for ocular lens material containing tris(trimethylsiloxy)silylpropyl(meth)acrylate (TRIS).

Applicant further submits that there are unexpected results commensurate in scope with claim 1. In particular, the claim shows the unexpected result that residual rates of unreacted monomers including not only hydrophilic monomer but also silicone monomer are decreased by combined use of the components (B) and (D). Evidence for the unexpected results is provided in the attached Declaration under 37 CFF 1.132 by Tsuyoshi WATANABE, signed November 26, 2010. Applicant here discusses how these results are unexpected over the cited references.

Regarding residual monomer in the cited references

In Iwata et al., there is the disclosure that "the lens thus obtained was dipped in ethyl alcohol overnight, then dipped in water followed by heating at 90 °C for 3 hours" (Example 8, Paragraph [0291]). All subsequent Examples (including Examples 14 and 35) employ an elution step with alcohol according to that in Example 8.

When materials comprising non-water soluble silicone component are used, it is necessary to remove unpolymerized silicone component in an elution step after a lens is obtained

by polymerization. Therefore, in order to remove non-water soluble silicone compound, it is essential in Iwata et al. to use an organic solvent.

Use of an organic solvent in the elution step causes various problems as well as imposing a cost for waste liquid disposal and an environment burden. For example, there are problems that the necessity of replacement procedure from organic solution into aqueous solution in order to use it as contact lens makes the manufacturing steps complicated, and that in addition to residual monomer, residual organic solvent must be checked to ensure safety of the product.

Unexpected effects of the present invention

On the other hand, the present invention has an unexpected effect on residual rates of unreacted monomers including not only hydrophilic monomer but also silicone monomer such as TRIS by using a pyrrolidone derivative (B) selected from the group consisting of 1-alkyl-3-methylene-2-pyrrolidone, 1-alkyl-5-methylene-2-pyrrolidone, and 5-alkyl-3-methylene-2-pyrrolidone (hereinafter refer to N-MMP) in combination with an N-substituted acrylamide (D). The combination of N-MMP (B) and N-substituted acrylamide (D) is excellent in polymerizability and copolymerizability with a silicone monomer compared with the combination of N-VP and the N-substituted acrylamide (D) (see Examples 1 to 3 and Comparative Example 1 in the specification of the application, pages 60-62).

Moreover, as described in Declaration under 37 CFR 1.132 attached hereto, the combined use of an N-substituted acrylamide (D) (DMAA) can lead to the more improved copolymerizability and the effectively decreased residual TRIS and N-MMP. Specifically, Experimental Examples A and C in the Declaration have (A) Macromer A1, (B) 1,3-MMP, (C)

TRIS, and (D) DMAA. These are compared to Examples B and D, in which the DMAA is substituted by 1,3-MMP (see Table 1 on page 2). In Experimental Examples A and C, which employ DMAA, the residual rates of TRIS are from about one-half to one-third those of Experimental Examples B and D, respectively (see Table 2). Similarly, the residual rates of 1,3-MMP are very low in Experimental Examples A and C compared with Experimental Examples B and D.

Such effects are exhibited **only** in the present invention comprising **all components (A) to (D)**, and these effects are therefore commensurate in scope with the present claims.

The Examiner indicates that Shibata et al. suggests that such pyrrolidones provide good polymerizability with (meth)acryloyl group, thereby decreasing poor optical and mechanical properties resulting from phase separation, and that, as well, no substantial elution of a non-crosslinked N-MMP polymer is observed. However, it is very significant that Shibata et al. does not teach non-water soluble silicone monomer such as TRIS and the combination with N-substituted acrylamide (D). Iwata et al. does not teach N-MMP as a pyrrolidone derivative.

It was known that TRIS has poor copolymerizability with hydrophilic monomer at the time of invention, which is demonstrated in the comparison of Examples 13 and 17 with Comparative Example 4 of the instant application.

Therefore, a person skilled in the art would not expect the significant effect of the present invention based on the disclosures of references. The results of the present invention, which are commensurate with the scope of claim 1, as amended, are unexpected over the cited references. Therefore, pending claims 1, 2, 4, 6, 8-10, and 16-18 are not obvious over Iwata et al. (US

2002/0016383), Shibata et al. (US 4,547,543), and Katagiri et al. (JP 06-214197), taken separately or in combination.

Claims 19-26 are rejected under 35 U.S.C. §103(a) as being unpatentable over Iwata et al. (US 2002/0016383) in view of Shibata et al. (US 4,547,543), when taken with Katagiri et al. (JP 06-214197) (English machine translation of Katagiri et al. (JP 06-214197) was used). (Office action page 6)

Claim 27 is rejected under 35 U.S.C. §103(a) as being unpatentable over Iwata et al. (US 2002/0016383) in view of Shibata et al. (US 4,547,543), as applied to claim 26 above, and further in view of Valiant, Jr. et al. (US 2002/0102415). (Office action page 9)

Claim 28 is rejected under 35 U.S.C. §103(a) as being unpatentable over Iwata et al. (US 2002/0016383) in view of Shibata et al. (US 4,547,543), as applied to claim 26 above, and further in view of Hayashi et al. (US 6,503,632). (Office action page 10)

Claims 29-30 are rejected under 35 U.S.C. §103(a) as being unpatentable over Iwata et al. (US 2002/0016383) in view of Shibata et al. (US 4,547,543), as applied to claim 26 above, and further in view of Walther et al. (US 6,379,004). (Office action page 11)

Claims 31-35 are rejected under 35 U.S.C. §103(a) as being unpatentable over Iwata et al. (US 2002/0016383) in view of Shibata et al. (US 4,547,543), as applied to claim 19 above, and further in view of Turek et al. (US 2002/0137811). (Office action page 12)

Claim 36 is rejected under 35 U.S.C. §103(a) as being unpatentable over Iwata et al. (US 2002/0016383) in view of Shibata et al. (US 4,547,543), as applied to claim 26 above, and further in view of Niwa et al. (US 6,503,632). (Office action page 13)

Claim 37 is rejected under 35 U.S.C. §103(a) as being unpatentable over Iwata et al. (US 2002/0016383) in view of Shibata et al. (US 4,547,543), when taken with Katagiri et al. (JP 06-214197) (English machine translation of Katagiri et al. (JP 06-214197) was used). (Office action page 13)

Reconsideration of these rejections is respectfully requested in view of the amendments to independent method claims 19 and 37. As discussed above, both claims 19 and 37 have been amended at step (a) to require “silicone compound (C) being tris(trimethylsiloxy)silylpropyl(meth)acrylates and an N-substituted acrylamide (D).”

Applicant has argued above with regard to the rejection of claim 1 over the combination of Iwata, Shibata and Katagiri, that neither Iwata et al. nor Shibata et al. teaches the combined use of components (B) and (D) according to the present invention for ocular lens material containing tris(trimethylsiloxy)silylpropyl(meth)acrylate (TRIS). Moreover, Applicant has argued, as evidenced by the data in the specification and the attached Declaration under 37 CFR 1.132, that there are unexpected results commensurate with the requirement for all of the recited components (A) to (D) in claim 1. Method claims 19 and 37 also require a step of obtaining a mixed solution comprising these components (A) to (D), which is then cured. The previously discussed unexpected results are therefore also commensurate in scope with claims 19 and 37. These results are also unexpected over the Valiant, Jr. et al., Hayashi et al., Walther et al., Turek et al., and Niwa et al. references.

Accordingly, claims 19 and 21-37 are not obvious over the cited references, taken separately or in combination.

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If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicant's undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, the applicant respectfully petitions for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

KRATZ, QUINTOS & HANSON, LLP


Daniel A. Geselowitz, Ph.D.

Agent for Applicants
Reg. No. 42,573

DAG/xl
Docket No. **050443**
4th Floor
1420 K Street, N.W.
Washington, D.C. 20005
(202) 659-2930



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Enclosure: Declaration Under 37 §1.132